FROM THE NAIC CONSUMER REPRESENTATIVES

June 1, 2023

To: Pharmacy Benefit Manager Regulatory Issues (B) Subgroup

RE: Consumer Representatives' Comments on "NAIC White Paper Draft-Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation"

On behalf of the undersigned Consumer Representatives to the National Association of Insurance Commissioners (NAIC), we appreciate the opportunity to comment on the **NAIC White Paper Draft-Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation.**

Due to the profound impact pharmacy benefit managers (PBMs) play in the drug pricing and delivery system and on consumer access and affordability of prescription medications we recommended that such a White Paper be drafted after a Draft PBM Model Act was not adopted by the NAIC. Over the almost two years since then, we appreciate the thoughtful approach the Subgroup has taken in soliciting comments from the consumer representatives and interested parties along with learning from states that have taken various steps in regulating PBMs and their activities.

We believe that through the Draft White Paper the Subgroup has achieved its goal to 1) analyze and assess the role of PBMs and others; 2) identify and examine state regulatory approaches towards PBMs, including the implications of the *Rutledge* decision; and 3) discuss challenges states have encountered in implementing PBM laws and regulations. In addition, as part of the Draft White Paper the Subgroup has proposed several next steps the NAIC can take to further address PBMs.

While we have some comments on the Draft White Paper that we detail below, in general we support many of the proposed recommendations in the White Paper**.** With adoption of this White Paper the NAIC has described the role of PBMs in the drug supply chain and steps some states have taken to regulate them, however, this issue certainly needs continued attention by the NAIC. We fully support continuation of the Subgroup, drafting PBM Model guidelines, updating Model 22, (which failed to address the role of PBMs in the development and management of health plan formularies), and continued dialogue among the states to learn what is occurring around the country and from the federal government relative to PBMs.

We trust through each of these proposed processes you will provide the opportunity for the NAIC consumer representatives to provide the consumer perspective, whose drug access and affordability are greatly impacted by PBMs. In fact, we would propose one addition to the Subgroup's recommendations: ***The NAIC should consider the impact of PBM and other regulations on consumer access to and affordability of prescription drugs.***

Specific Draft White Paper Comments

While we believe the Subgroup has adequately addressed its charges and has done so in a rather neutral manner, we do offer some specific comments on the Draft White Paper. We list them below in the order in which they appear in the document and not in the order of importance to consumers.

Key Players in Pharmaceutical Drug Pricing Ecosystem

We appreciate how the Draft White Paper begins by describing the important role affordability and access to medications are to consumers. However, we believe that this section can be strengthened by further articulating the importance of prescription drugs as a vital component to current medical care. (page 4):

> Pharmaceutical drugs are vital to both longevity and quality of life for many individuals. *Prescription drugs are prescribed to address a specific illness or disease or used for preventive purposes. It is therefore important for consumers to receive these medications in the manner prescribed by their provider in order to address, treat, or prevent illness or disease.*

Interrelation of Parties in the Chain and Transaction Costs

Pharmacy and consumer

We recommend strengthening the section to provide further elaboration on the role of the pharmacy with respect to consumer access to prescription drugs, and mentioning the use of deductibles. (page 9)

> The pharmacy provides drugs directly to the consumer and collects certain cost sharing that may include co-pays or co-insurance *after the consumer meets their deductible (if any). The pharmacy may also advise consumers of lower-cost prescription drug alternatives and may provide consumers with information on how to file an appeal, if necessary.*

Pharmacy Benefit Chain

Manufactures and consumer

The sentence describing state laws and copay assistance fails to identify the significant action PBMs are taking by implementing copay accumulators. We suggest (as noted below) that the Draft White Paper include a discussion about copay accumulator, copay maximizer and alternative funding programs. However, we believe this information would be more appropriately included on page 24. We therefore recommend that references to copay accumulator programs be deleted in this section. (page 9)

> Pharmaceutical manufacturers can offer coupons or occasionally free samples of medications to consumers. The coupons can reduce a consumer's cost sharing below that which they would have paid had they used their pharmacy benefit plan.[40] ~~If the coupon constitutes a third-party paying the consumer's cost share, some state laws require insurers to count this payment towards the consumer's deductible and pharmacy benefit maximum out of pocket amount.~~

Medicare Part D

We note that the Medicare Part D benefit is an optional benefit available to all Medicare enrollees and not only those over the age of 65. Therefore, we recommend the Draft White Paper language be amended accordingly (page 12):

Medicare Part D is a~~n optional~~ *voluntary outpatient prescription drug benefit available to all Medicare enrollees and operated by private plans that contract with Medicare*~~, federally supported prescription drug benefit available to Americans over the age of 65~~. The program's authorizing legislation incorporates the federal preemption language from the Medicare Part C, or "Medicare Advantage (MA)" program, which provides: "the standards established under this part shall supersede any state law or regulation (other than state licensing laws or state laws relating to plan solvency) with respect to MA plans which are offered by MA organizations under this part."[58]

Medicaid

After the discussion that state Medicaid programs utilize DUR Board and P&T Committees, we believe prior authorization and other utilization management requirements should also be included. (page 14)

To address rising costs, Congress passed legislation enacting the Medicaid Drug Rebate Program in 1990. Under this program, pharmaceutical companies sign a master rebate agreement with the CMS, which administers the Medicaid program at the federal level. These rebates result in cost savings on prescription drugs that are paid for under the Medicaid program and are shared by both the state Medicaid agency and the CMS. State Medicaid programs are required to provide a pathway to coverage for any drug whose manufacturer has signed a rebate agreement with the CMS. Therefore, state Medicaid programs do not have the flexibility that insurers in the private market do to implement strict formularies to control prescription drug spending. Instead, state Medicaid programs are allowed to negotiate additional "supplemental rebates" with pharmaceutical manufacturers individually, and to develop preferred drug lists*, and impose utilization management tools such as prior authorization requirements* in consultation with state Drug Utilization Review (DUR) Boards and Pharmacy and Therapeutics (P&T) Committees.

Rebates

It should be noted that consumer utilization of prescription drugs generates the rebates for the plan, which are for the benefit of all enrollees in the plan regardless of whether they use prescription drugs. (page 15)

The negotiation between a pharmaceutical manufacturer and PBM may result in a rebate. The rebate flows back to the PBM from the manufacturer usually based on the volume of prescriptions generated by the manufacturer's drug's placement on the PBM's formulary. The PBM may pass the rebate on to the health benefit plan according to their shared contract, which may allow the PBM to keep a percentage of the rebate, but it is possible the PBM keeps the entire rebate with no direct benefit to the plan or the consumer.[72] *While these rebates are generated by consumers who utilize prescription drugs, the benefits associated with these rebates are shared by other enrollees, the plan or the PBM.*

State Laws that Operate in the Supply Chain

We suggest adding to the White Paper the extensive document that Jolie Matthews has prepared that includes all relevant state PBM laws. We do not believe the ones included truly represent the full range of laws and regulations that have been passed or promulgated by the states. (page 23)

Other Relevant State Laws and Proposed Laws

We appreciate the Draft White Paper provides additional information on various PBM practices in this section. (page 24) However, we would caution that this section should not be limited only to existing or proposed state laws. Therefore, we suggest changing the title to "Other Relevant Policy Proposals".

In addition, we believe the Draft White Paper should also incorporate a discussion of other policies and practices that PBMs perform that have a direct impact on consumers. For example, we would recommend inclusion of the following:

Utilization management tools: PBMs also impose utilization management tools on certain prescription drugs in order to encourage or discourage their use. Utilization management tools can include the creation of the plan formulary, which assigns prescription drugs to specific formulary tiers and assigns a corresponding cost-sharing so that lower-tiered prescription drugs have a lower cost-sharing. Utilization management tools also include prior authorization, step therapy, and dose restrictions. For a definition of these practices, see NAIC Model 22.

Copay accumulator adjustment programs: Under these programs the manufacturer copay assistance is collected by the health plan/PBM but does not count towards the consumer's deductible or out-of-pocket costs. Several states have laws that prohibit these practices and require that the copay assistance count towards the consumer's maximum out-of-pocket costs.

Copay maximizer programs: Under these programs, the manufacturer copay assistance is collected by the health plan/PBM and the value of the assistance is applied evenly throughout the plan year. In some instance, specific drugs are identified as non-essential health benefits. However, like copay accumulator adjustment programs, the amount of the assistance does not count toward the consumer's deductible or out-of-pocket costs.

Alternative Funding Programs: These programs are generally seen in self-insured plans and some state or municipal government plans. Under this program, certain drugs (either specific medications or entire categories or classes of medication) are reclassified as "non-essential" and are no longer considered as part an Essential Health Benefit. From a consumer perspective, not only are these drugs not a covered benefit, but any cost-sharing incurred by the consumer would not count toward the individual's maximum out-of-pocket costs. If an individual is prescribed a drug that is part of the alternative funding program, the individual's health plan works with a separate vendor to take advantage of needs-based programs, charitable organizations or through other means to obtain the drug.

Federal Interest and Possible Regulations

Since the Draft was released, additional actions have been taken in both House and Senate Committees relative to PBMs. We recognize that the Congressional action is concurrent with the development of the NAIC White Paper and therefore it may not be possible to include an accurate account of the status of Congressional action. However, we recommend that prior to the finalization of the White Paper additional references be included to reflect the current Congressional action as of a specific date. (pages 25-27)

We appreciate that the NAIC is addressing the regulation of PBMs since they play such an important role in consumer affordability and access of prescription medications. **We urge the NAIC to move**

quickly in adopting the White Paper and moving forward with its recommendations as soon as possible.

For any questions, please contact Carl Schmid, HIV+Hepatitis Policy Institute at cschmid@hivhep.org. Thank you very much.

Sincerely,

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